

Attachment 1: 510(k) Summary:

K003041 PAGE 1 of 2

This summary is provided as part of this Premarket Notification in compliance with 21CFR, Section 807.92.

FEB - 7 2001

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Contact person: Villy Braender, Quality Assurance Manager
Date prepared: 27. September, 2000

Trade name: Ultrasound Scanner Type 2101
Common name: Diagnostic Ultrasound System
Classification names:
Ultrasonic Pulsed Echo Imaging System (90 IYO, CFR 892.1560)
Diagnostic Ultrasonic Transducer (90 ITX, CFR 892.1570)

Identification of predicate, legally marketed device:
Siemens Medical Systems: Sonoline Elegra Diagnostic Ultrasound System (K980557)

Device description:

2101 supports the following scanning modes and combinations thereof:
B-mode M-mode. An optional ECG signal can be superimposed the ultrasound information in all modes and mode combinations.
The system can perform simple geometric measurements, and perform calculations in the areas of Urology, Cardiology and OB/GYN applications.
The system can guide biopsy- and puncture needles.

Transducers

Transducers are linear and convex arrays and mechanical sector.
The patient contact materials comply with ISO10993-1
All transducers used together with 2101 are Track 3 transducers.

Acoustic output

The system will assure that the acoustic output always will stay below the pre-amendments upper limits i.e. $Ispta \leq 720 \text{ mW/cm}^2$ and $MI \leq 1.9$ (Track 3, non ophthalmic).
The Thermal Index values are maximum 6.0, i.e. $TI \leq 6.0$

Clinical measurement accuracy.

Clinical measurements and calculations are described and accuracies are provided in the User Guide.

Thermal, mechanical and electrical safety.

The scanner 2101 has been tested by a recognized, certified body according to IEC 60601-1.

Acoustic Output Reporting

The Acoustic Output Reporting is made according to the standards required by "Information for Manufacturers Seeking Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, CDRH, September 30, 1997"

The acoustic output is measured and calculated according to: "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (AIUM 1998).

Intended use.

See comparison below

Technological characteristics compared to the predicate device.

The predicate device has the same major technological characteristics as the subject device, see comparison below.

Comparison with K980557, Sonoline Elegra (Siemens Medical Systems).

	Type 2101 in this application	K980557, Sonoline Elegra
Intended uses	Abdominal, Cardiac, Fetal, Intraoperative, Neurosurgery, Obstetrics, Pediatrics, Transrectal, Small organs, Transvaginal, Musculoskeletal (superficial, conventional)	General Radiology, Abdominal, Intraoperative, Small parts, transcranial, OB/GYN, Neonatal/Adult Cephalic, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, Peripheral Vascular
General device description	B,M and combination modes, Track 3 (Index display). Measurements	B,M Color, PW, CW and combination modes. Track 3 (Index display). Measurements.
Acoustic output	$Ispta \leq 720 \text{ mW/cm}^2$ and $MI \leq 1.9$ (Track 3, non ophthalmic). $TI \leq 6.0$	Not in 510(k) summary, except that it has index display according to Display standard.
General safety and effectiveness	UL2601, CSA22.2 No 601-1, EN60601, 93/42/EEC Medical Devices Directive, AIUM/NEMA Display standard, EN/ISO 10993-1	UL2601, CSA22.2 No 601-1, EN60601, 93/42/EEC Medical Devices Directive, AIUM/NEMA Display standard
Labeling	Please refer to section 4.8	Not in 510(k) summary)

Conclusion: The device 2101 in this application has similar intended uses, and in particular the subject for the application, musculo-skeletal is the same. Also both devices have been previously cleared for 'small parts'(organs), an indication very close to 'musculo-skeletal, superficial'). B-K Medical A/S therefore believes, that 2101 is substantially equivalent to K980557.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 7 2001

Villy Braender
Official Correspondent
B-K Medical A/S
Sandtoften 9, DK2820
Gentofte
DENMARK

Re: K003041
Ultrasound Scanner Type 2101
(addition of musculo-skeletal indication)
Dated: January 12, 2001
Received: January 16, 2001
Regulatory class: II
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1570/Procode: 90 ITX

Dear Mr. Braender:

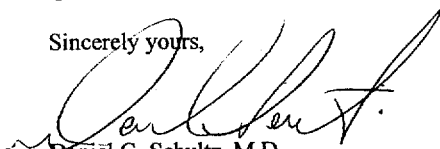
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

4.3 Indications for Use Statement

K003041

510(k)Number: K003041
(if known)

Device Name : **Ultrasound scanner Type 2101**


Indications for Use :

**Ultrasound scanner and transducers for B, M and combined mode imaging.
Guidance of biopsy needles, geometrical measurements and calculation of parameters.
Non monitoring ECG for superimposing the ultrasound information.**

**Clinical applications: Abdominal, Cardiac, Fetal, Intraoperative, Neurosurgery,
Obstetrics, Pediatrics, Transrectal, Small organs, Transvaginal, Musculoskeletal.**

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003041

Prescription Use ☒
(Per 21 CFR 801.109)

OR Over-The-Counter Use ☐

K003041

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 2101
 Transducer: 8805

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)	P	P				P (B+M)	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N	N				N(B+M)	
	Musculo-skel. (Superficial)	N	N				N(B+M)	
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA(K991937); E = added under Appendix E

*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: Small Organ: Breast, testis, penis, thyroid, parathyroid, salivary glands, lymph nodes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

David R. Ferguson

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K003041

K003041

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 2101
 Transducer: 8804

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P				P (B + M)	
	Small Organ (Specify)	P	P				P (B + M)	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N	N				N(B + M)	
	Musculo-skel. (Superficial)	N	N				N(B + M)	
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA(K991937); E = added under Appendix E

*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: Small Organ: Breast, testis, penis, thyroid, parathyroid, salivary glands, lymph nodes

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

David L. Segman
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K003041

K003041

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 2101
 Transducer: 8664

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P				P (B + M)	
	Small Organ (Specify)	P	P				P (B + M)	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N	N				N(B + M)	
	Musculo-skel. (Superficial)	N	N				N(B + M)	
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA(K991937); E = added under Appendix E

*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: Small Organ: Breast, testis, penis, thyroid, parathyroid, salivary glands, lymph nodes

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number

K003041

K003041

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 2101
 Transducer: 8660

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	P	P				P (B+M)	
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P				P (B+M)	
	Small Organ (Specify)	P	P				P (B+M)	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N	N				N(B+M)	
	Musculo-skel. (Superficial)	N	N				N(B+M)	
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA(K991937); E= added under Appendix E

*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: Intraoperative: Breast, liver, pancreas, biliary system
 Small Organ: Breast, testis, penis, thyroid, parathyroid, salivary glands, lymph nodes

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David L. Jensen
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K003041

Prescription Use (Per 21 CFR 801.109)

K003041

Diagnostic Ultrasound Indications for Use Form

System: 2101

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		X	X						X (B+M)	
Abdominal		X	X						X (B+M)	
Intraoperative (specify)		X	X						X (B+M)	
Intraoperative Neurological		X	X						X (B+M)	
Pediatric		X	X						X (B+M)	
Small Organ (specify)		X	X						X (B+M)	
Neonatal Cephalic										
Adult Cephalic										
Cardiac		X	X						X (B+M)	
Transesophageal										
Transrectal		X	X						X (B+M)	
Transvaginal		X	X						X (B+M)	
Transurethral		X	X						X (B+M)	
Intravascular										
Peripheral Vascular										
Laparoscopic		X	X						X (B+M)	
Musculo-skeletal Conventional		X	X						X (B+M)	
Musculo-skeletal Superficial		X	X						X (B+M)	
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) *[Signature]*
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K003041

Prescription Use (Per 21 CFR 801.109)